REGISTRATION PACKAGE


# October 10 – 12, 2000
# Sheraton Imperial Hotel and Convention Center
# Research Triangle Park, North Carolina

*Organized by the*

National Institute of Environmental Health Sciences
National Toxicology Program
Research Triangle Park, NC

**NTP** **NIEHS**

*Sponsored by the*

U.S. Environmental Protection Agency
Washington, DC

*and the*

National Institute of Environmental Health Sciences
National Toxicology Program
Research Triangle Park, NC

## Purpose

The U.S. Environmental Protection Agency (EPA) has asked the National Toxicology Program (NTP) to establish an independent panel of scientists to review the scientific evidence related to low-dose effects of endocrine disruptors and to consider their implications for the development, validation, and interpretation of test protocols for reproductive and developmental toxicity. If this panel concludes that significant effects may occur at low doses and that the standard dose-setting paradigm is inadequate to detect such effects, then the EPA intends to pursue through a separate forum, the question of how to test for such effects including endpoints to be measured, dose-setting protocols, and appropriate test methods. If the Panel believes that the current data are inconclusive, it will be asked to describe specific research that would resolve the ambiguities.

## Peer Review Goals

Analyses will focus on interpretation of selected major studies (excluding studies on dioxin and dioxin-like compounds) showing or refuting effects at low doses for endocrine disruptors on reproductive and developmental endpoints. The intent is to examine data supporting the presence or absence of low-dose effects in specific studies and then evaluate the likelihood and significance of these and/or other potential low-dose effects for humans. A main topic to be addressed is defining the shape of the dose/response curves for endocrine-active substances in the low-dose region. This analysis and evaluation will be accomplished through a three-day scientific peer review that includes plenary sessions and several breakout sessions. This peer review is open to the public.

## Peer Review Panel

The peer review panel will be subdivided into five subpanels:

1. Bisphenol A
2. Other Environmental Estrogens and Estradiol
3. Androgens and Anti-Androgens
4. Biological Factors (*i.e*. confounders: diet, strain, etc.) and Study Design
5. Statistics and Dose-Response Modeling

## Subpanels

The subpanels will review all evidence, including relevant pharmacokinetic and mechanistic information, that may have a bearing on the low-dose issue. In addition, they will consider the consistency in the data (within and across studies), the strength and specificity of the evidence for low-dose effects, the evidence for defining the shape of the dose-response curves in the low-dose region, and the biologic plausibility of the reported effect(s). The subpanel will identify research gaps and, as possible, ways to address those gaps. Subpanels 1-4 will prepare reports of their conclusions, including areas of consensus and disagreement relative to low-dose effects on reproduction and development, and identify research needs that would help resolve ambiguities. Prior to the peer review, Subpanel 5 will reevaluate selective laboratory data and analyze dose-response relationships from identified studies and make that information available to Subpanels 1-4 for inclusion in their evaluations. At the peer review, members of Subpanel 5 will be reassigned to Subpanels 1-4.

## Observers and Public Comments

The public is invited to attend the peer review and the number of observers will be limited only by the available space. A public comment session on Tuesday, October 10th will provide an opportunity for interested persons or groups to present their views and comments to the Panel (limit one speaker per group). The public is invited to present oral comments or to submit comments in writing. Oral presentations will be limited to five minutes per speaker to allow for a maximum number of presentations. Individuals presenting oral comments are asked to provide a hard copy of their statement at registration. For planning purposes, persons wishing to give oral comments are asked to register by October 1, although registration will also be accepted on-site. Persons registering for oral comments or submitting written remarks are asked to include their contact information (name, address, affiliation, telephone, fax, e-mail). Written comments for consideration by the Panel at the peer review are welcome and must be received by October 1, 2000.

## Accomodations

Hotel reservations can be made directly with the Sheraton Imperial Hotel, 919-941-5050. A block of rooms is being held through September 9, 2000. Identify yourself as attending the Low-dose Review.

*Other nearby hotels:*

*Holiday Inn - 919-941-6000*
*4810 New Page Road*
*Research Triangle Park, NC*

*Comfort Suites – 919-474-9400*
*5219 Page Road*
*Research Triangle Park, NC*

# Tentative Agenda

**Tuesday, October 10, 2000**

| | |
|---|---|
| 8:30 - 9:00 am | Scope of Review |
| 9:00 – 9:15 am | Charge to Panel |
| 9:15 – 10:30 am | Body of Knowledge Presentation and Discussion<br>Dr. Frederick S. vom Saal, University of Missouri |
| 10:30 – 11:00 am | **Break** |
| 11:00 am – 12:15 pm | Body of Knowledge Presentation and Discussion<br>Dr. John Ashby, Zeneca, Central Toxicology Laboratory, United Kingdom |
| 12:15 – 1:15 pm | **Lunch** |
| 1:15 – 2:30 pm | Body of Knowledge Presentation and Discussion<br>Dr. K. Barry Delclos, National Center for Toxicological Research |
| 2:30 – 3:45 pm | Body of Knowledge Presentation and Discussion<br>Dr. John C. O'Connor, DuPont Haskell Laboratory<br>Summary of Other Bodies of Knowledge Studies |
| 3:45 – 4:15 pm | **Break** |
| 4:15 – 5:00 pm | Summary of Other Bodies of Knowledge Studies |
| 5:00 – 6:00 pm | Public Comments |
| 6:00 – 8:00 pm | **Dinner** |
| 8:00 – 9:00 pm | Subpanels: Initial Meeting |

**Wednesday, October 11, 2000**

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|---|---|
| 8:30 am – 5:00 pm | Subpanel Meetings<br>1. Bisphenol A<br>2. Other Environmental Estrogens and Estradiol<br>3. Androgens and Anti-Androgens<br>4. Biological Factors (*i.e*. confounders: diet, strain, etc.) and Study Design |
| 10:00 – 10:30 am | **Break** |
| 12:00 – 1:00 pm | **Lunch** |
| 2:30 – 3:00 pm | **Break** |

**Thursday, October 12, 2000**

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|---|---|
| 8:30 – 10:00 am | Subpanel Meetings |
| 10:00 – 10:30 am | **Break** |
| 10:30 am – 12:00 pm | Presentation and Discussion of Subpanel Reports |
| 12:00 – 1:00 pm | **Lunch** |
| 1:00 – 2:30 pm | Presentation and Discussion of Subpanel Reports |
| 2:30 – 3:00 pm | **Break** |
| 3:00 – 5:00 pm | Presentation and Discussion of Subpanel Reports |

**Registration Form**

**NTP/NIEHS Endocrine Disruptors Low-Dose Peer Review**

(Open to the public, limited only by space available)

Sheraton Imperial Hotel and Convention Center
Research Triangle Park, NC
October 10-12, 2000

**(Please type or print clearly)**

| Last Name | First Name | Middle Initial |
|---|---|---|

| Institution | Department |
|---|---|

| Address | City | State | Zip Code |
|---|---|---|---|

| Office Phone | Fax Number | E-mail Address |
|---|---|---|

## Registration Fee: **$90.00**

You may **register on line** (click here) or mail your registration, with check or money order, no later than September 29, 2000, to:

NTP Liaison Office
NTP/NIEHS
P.O. Box 12233, MD: A3-01
Research Triangle Park, NC 27709
(919) 541-0530

**Please make checks payable to:**
**NTP/NIEHS Low-Dose Peer Review**

Subpanels: (please mark first and second choice)

1. Bisphenol A _____
2. Other Environmental Estrogens and Estradiol _____
3. Androgens and Anti-Androgens _____
4. Biological Factors and Study Design _____

Public Comment Session:
Participate (limit 5-minute oral presentation) _____ YES _____ NO